

**Listing of Claims:**

This Listing of Claims will replace all prior versions and listings of claims in the application:

**Claims**

1. (Previously Presented) An assembly with proximal and distal ends for bone, tissue and/or duct dilatation of a living being comprising in combination: (a) a tube having a fluid inlet at a tube proximal end, a fluid outlet at a tube distal end, and a tube lumen extending between the fluid inlet and the fluid outlet; (b) an inflatable and deflatable balloon element having a balloon interior and balloon proximal and distal ends in fluid communication with the tube lumen; and, (c) balloon tensioning and/or balloon wrapping device(s) for stretching the balloon element and/or folding, pleating or wrapping the balloon element before and/or after inflation to facilitate insertion and/or removal of the balloon element through a narrow diameter duct, access channel or canula, said balloon tensioning and/or balloon wrapping device(s) comprising at least a spring element, located at the proximal end of the assembly proximal of the fluid inlet and fluidically isolated from the tube lumen, which spring element can alternately be compressed or decompressed, said spring activating an associated rod extending through at least a part of said tube lumen and said balloon interior such that compression of the spring element toward the distal end applies an axial stretching force to the balloon and

decompression of the spring element away from the distal end releases the axial stretching force.

2. (Previously Presented) An assembly according to claim 1 wherein said balloon element is capable of being inflated to a working diameter of about 12 mm to about 25 mm.

3. (Previously Presented) An assembly according to claim 1 wherein said balloon element is capable of being inflated to a working pressure of about 200 – 400 psi over a relatively short balloon working length.

4. (Previously Presented) An assembly according to claim 1 wherein said balloon element is stretched and/or folded, pleated or wrapped to a diameter of about 4 – 5 mm or less for insertion through and/or removal from said duct, access channel or canula.

5. (Previously Presented) An assembly according to claim 1 wherein said balloon tensioning and/or balloon wrapping device(s) is/are selected from the group consisting of active and passive tensioning and wrapping devices.

6. (Previously Presented) An assembly according to claim 1 wherein, upon inflation to its working pressure, the balloon element maintains a high degree of puncture and abrasion resistance.

7. (Previously Presented) An assembly according to claim 1 wherein the balloon element is mounted at the distal end of the tube, and the proximal end of the balloon element is bonded to or integrally connected to the fluid outlet of the tube to create a passage through the tube lumen and the balloon interior.

8. (Previously Presented) An assembly according to claim 7 wherein the distal end of the balloon element is sealed, and a rod extends through the passage to the sealed distal end of the balloon element.

9. (Previously Presented) An assembly according to claim 8 wherein axial force can be applied manually and/or automatically to push the rod against the sealed distal end of the balloon element causing tension and axial elongation of the balloon element.

10. (Previously Presented) An assembly according to claim 9 wherein the rod is not attached to the balloon element.

11. (Previously Presented) An assembly according to claim 9 wherein the rod is attached to or otherwise engages the balloon element.

12. (Previously Presented) An assembly according to claim 11 further wherein rotational force can be applied manually or automatically to rotate the rod relative to a free-standing position causing the balloon element at least in part to wrap around the rod.

13. (Previously Presented) An assembly according to claim 9 further wherein said spring is compressed to apply axial tensioning and elongation to the balloon element.

14. (Previously Presented) An assembly according to claim 11 further wherein said rod is spring loaded to apply rotational tensioning to the balloon element.

15. (Previously Presented) An assembly according to claim 13 further wherein said rod is spring loaded to apply rotational tensioning to the balloon element.

16. (Previously Presented) An assembly according to claim 11 wherein said rod engages a compressive or rotational spring element.

17. (Canceled)

18. (Previously Presented) An assembly according to claim 1 wherein the balloon tensioning and/or wrapping device is manually actuated.

19. (Previously Presented) An assembly according to claim 8 wherein said rod is adjustable in length.

20. (Previously Presented) An assembly according to claim 1 further comprising elastomeric tubing placed over said balloon element.

21. (Previously Presented) An assembly according to claim 1 further wherein the exterior of said balloon element is coated with a material to improve puncture and abrasion resistance.

22. (Previously Presented) An assembly according to claim 11 further comprising at least a canula element wherein at least one end of the balloon element extends into or completely through said canula element when the balloon element is positioned in a cavity to be dilated.

23. (Previously Presented) An assembly according to claim 22 further wherein said canula element restricts expansion forces of the balloon element during inflation of the balloon element.

24. (Previously Presented) An assembly according to claim 8 wherein, after the balloon element is inserted in a cavity to be dilated and is inflated to working pressure for a sufficient period of time to achieve a desired degree of cavity dilatation, the interior of the inflated balloon element is filled in situ with a cement material.

25. (Previously Presented) An assembly according to claim 24 wherein the rod is removed from the balloon interior before the balloon element is filled with a cement material.

26. (Previously Presented) An assembly according to claim 24 wherein the rod has a hollow interior that acts as a vent for working fluid in the balloon element while the balloon element is filled with a cement material.

27. (Previously Presented) An assembly according to claim 24 wherein the tube is detached from the balloon element after the balloon element is filled with the cement material.

28. (Previously Presented) An assembly according to claim 1 wherein said balloon element comprises a multi-lumen balloon.

29. (Previously Presented) An assembly according to claim 11 wherein said rod is spring loaded to apply automatic axial tensioning to the balloon element and

comprises an accessible proximal end for optional manual rotational tensioning of the balloon element.

30. (Previously Presented) An assembly according to claim 1 further comprising a pre-curved guidewire in the interior of the balloon element.

31. (Previously Presented) An assembly according to claim 8 wherein said rod comprises concentric inner and outer tubular members which are rotatable relative to one another and said balloon element is attached to or engages one of said tubular members whereby rotational forces can be applied to cause the balloon element at least in part to wrap around one of said tubular members.

32. (Previously Presented) An assembly according to claim 8 further wherein said rod is pre-curved and consists essentially of a material having memory properties.

33. (Previously Presented) An assembly according to claim 1 wherein said balloon element is pre-curved.

34. (Previously Presented) An assembly according to claim 1 wherein said balloon element consists essentially of a non-elastomeric material.

35. – 90. (Canceled)

91. (Previously Presented) An assembly with proximal and distal ends for bone, tissue and/or duct dilatation of a living being comprising in combination:
- (a) an inflatable and deflatable medical balloon having a balloon interior;
  - (b) a conduit defining a channel for accessing the balloon interior from a location outside a living body when the balloon is positioned inside the living body;
  - (c) a rod having proximal and distal ends extending through the channel to the balloon at the distal end of the rod;
  - (d) a spring element capable of temporarily applying axial and/or rotational forces to the balloon by means of the rod causing the balloon to elongate, or to wrap around the rod, or both, said spring element being housed in a spring housing section located at the proximal end of the assembly and fluidically isolated from the channel; and,
  - (e) a knob element connected to the proximal end of the rod for manual manipulation of the rod.

92. (Previously Presented) An assembly according to claim 91 wherein said balloon is capable of being inflated to a working diameter of about 12 mm to about 25 mm.



93. (Previously Presented) An assembly according to claim 91 wherein said balloon is capable of being inflated to a working pressure of about 200 – 400 psi over a relatively short balloon working length.

94. (Previously Presented) An assembly according to claim 91 wherein said balloon is stretched and/or folded, pleated or wrapped to a diameter of about 4 – 5 mm or less for insertion through and/or removal from a duct, access channel or canula.

95. (Previously Presented) An assembly according to claim 91 wherein, upon inflation to its working pressure, the balloon maintains a high degree of puncture and abrasion resistance.

96. (Previously Presented) An assembly according to claim 91 wherein the balloon has a sealed distal end.

97. (Previously Presented) An assembly according to claim 91 wherein the rod is attached to or otherwise engages the balloon.

98. (Previously Presented) An assembly according to claim 91 further wherein said spring is compressed toward the distal end to apply axial tensioning and elongation to the balloon.

99. (Previously Presented) An assembly according to claim 91 further wherein said rod is spring loaded to apply rotational tensioning to the balloon.

100. (Previously Presented) An assembly according to claim 98 further wherein said rod is spring loaded to apply rotational tensioning to the balloon.

101. (Previously Presented) An assembly according to claim 91 wherein said rod is adjustable in length.

102. (Previously Presented) An assembly according to claim 91 further comprising elastomeric tubing placed over said balloon.

103. (Previously Presented) An assembly according to claim 91 further wherein an exterior surface of said balloon is coated with a material to improve puncture and abrasion resistance.

104. (Previously Presented) An assembly according to claim 91 further comprising at least a canula element wherein at least one end of the balloon extends into or completely through said canula element when the balloon is positioned in a cavity to be dilated.

105. (Previously Presented) An assembly according to claim 91 further wherein said canula element restricts expansion forces of the balloon during inflation of the balloon.

106. (Previously Presented) An assembly according to claim 91 wherein, after the balloon is inserted in a cavity to be dilated and is inflated to working pressure for a sufficient period of time to achieve a desired degree of cavity dilatation, the interior of the inflated balloon is filled in situ with a cement material.

107. (Previously Presented) An assembly according to claim 91 wherein the rod is removed from the balloon interior before the balloon is filled with a cement material.

108. (Previously Presented) An assembly according to claim 91 wherein the rod has a hollow interior that acts as a vent for working fluid in the balloon while the balloon is filled with a cement material.

109. (Previously Presented) An assembly according to claim 107 wherein the conduit is detached from the balloon after the balloon is filled with the cement material.

110. (Previously Presented) An assembly according to claim 91 wherein said balloon comprises a multi-lumen balloon.

111. (Previously Presented) An assembly according to claim 91 further comprising a pre-curved guidewire in the interior of the balloon.

112. (Previously Presented) An assembly according to claim 91 wherein said rod comprises concentric inner and outer tubular members which are rotatable relative to one another and said balloon is attached to or engages one of said tubular members whereby rotational forces can be applied to cause the balloon at least in part to wrap around one of said tubular members.

113. (Previously Presented) An assembly according to claim 91 further wherein said rod is pre-curved and consists essentially of a material having memory properties.

114. (Previously Presented) An assembly according to claim 91 wherein said balloon is pre-curved.

115. (Previously Presented) An assembly according to claim 91 wherein said balloon consists essentially of a non-elastomeric material.

116. (Previously Presented) An assembly according to Claim 1 further comprising a spring housing section having proximal and distal ends for housing the spring element, the spring housing including a threaded portion at its proximal end.

117. (Previously Presented) An assembly according to claim 116 further comprising a threaded cap element sized to mate with the threaded portion of the spring housing.

118. (Previously Presented) An assembly according to claim 117 wherein the cap element includes a centrally-located axial bore to accommodate the rod.

119. (Previously Presented) An assembly according to claim 1 wherein the rod has a knob element attached at its proximal end.

120. (Previously Presented) An assembly according to claim 118 wherein the rod includes a section that extends through and beyond the cap element.

121. (Previously Presented) An assembly according to claim 120 wherein a knob element is connected to the rod at the section that extends beyond the cap element.

122. (Previously Presented) An assembly according to claim 120 further comprising a sealing gasket between the spring element and the threaded portion of the spring housing, said gasket having a centrally located aperture in alignment with the axial bore to accommodate the rod.

123. (Previously Presented) An assembly according to claim 116 further comprising a disc element located between the spring element and the distal end of the spring housing, said disc element being connected to the rod and sized to slide inside the spring housing along with movement of the rod so as to compress the spring element by displacement of the disc in the proximal direction or to decompress the spring element by displacement of the disc in the distal direction.

124. (Previously Presented) An assembly with proximal and distal ends for bone, tissue and/or duct dilatation of a living being comprising in combination: (a) a tube having a fluid inlet at a tube proximal end, a fluid outlet at a tube distal end, and a tube lumen extending between the fluid inlet and the fluid outlet; (b) an inflatable and deflatable balloon element having a balloon interior and balloon proximal and distal ends in fluid communication with the tube lumen; and, (c) balloon tensioning and/or balloon wrapping device(s) for stretching the balloon element and/or folding, pleating or wrapping the balloon element before and/or after inflation to facilitate insertion and/or removal of the balloon element through a narrow diameter duct, access channel or canula, said balloon tensioning and/or balloon wrapping device(s) comprising at least a spring element, located at the proximal end of the assembly proximal of the fluid inlet and fluidically isolated from the tube lumen, which spring element can alternately be compressed or decompressed, said spring activating an associated rod extending through at least a part of said tube lumen and said balloon interior such that compression of the spring element toward the distal end applies an axial stretching force to the balloon and

decompression of the spring element away from the distal end releases the axial stretching force;

the assembly further comprising a spring housing section having proximal and distal ends for housing the spring element, the spring housing including a threaded portion at its proximal end and also comprising a threaded cap element sized to mate with the threaded portion of the spring housing, wherein the cap element includes a centrally-located axial bore to accommodate the rod, the rod including a section that extends through and beyond the cap element; and,

the assembly further comprising a sealing gasket between the spring element and the threaded portion of the spring housing, said gasket having a centrally located aperture in alignment with the axial bore to accommodate the rod.

125. (Previously Presented) An assembly according to claim 124 wherein the cap element is loosely threaded onto the spring housing such that there is no compression of the spring element and substantially no axial force is applied by the rod to the balloon element, which is in an uninflated state.

126. (Previously Presented) An assembly according to claim 124 wherein the cap element is screwed onto the spring housing thereby at least partially compressing the spring element, while the balloon element is in an uninflated state.

127. (Previously Presented) An assembly according to claim 124 wherein the cap element is screwed onto the spring housing thereby at least partially compressing the spring element, and the balloon element is at least partially inflated such that the distal end of the balloon applies an axial force to the rod causing it to displace the disc element in a proximal direction so as to additionally compress the spring element beyond the compression obtained by screwing the cap element onto the spring housing.

128. (Previously Presented) An assembly according to claim 124 wherein the cap element is screwed onto the spring housing thereby at least partially compressing the spring element, and the balloon element is fully inflated such that the distal end of the balloon applies an axial force to the rod causing it to displace the disc element in a proximal direction so as to additionally compress the spring element beyond the compression obtained by screwing the cap element onto the spring housing.

129. (Previously Presented) An assembly according to claim 127 further comprising a source of pressurized fluid which is supplying the pressurized fluid to the balloon element and causing additional displacement of the disc element in a proximal direction.

130. (Previously Presented) An assembly according to claim 127 wherein pressurized fluid is not being supplied to the balloon element causing the balloon element to be in a deflating state which releases the axial force applied by the distal end of the



balloon to the rod such that the force exerted by the compressed spring element on the rod becomes greater than the force of the deflating balloon and the disc element is displaced in a distal direction thereby stretching and tensioning the balloon element.

131. (Previously Presented) An assembly according to Claim 91 further comprising a spring housing section having proximal and distal ends for housing the spring element, the spring housing including a threaded portion at its proximal end.

132. (Previously Presented) An assembly according to claim 131 further comprising a threaded cap element sized to mate with the threaded portion of the spring housing.

133. (Previously Presented) An assembly according to claim 132 wherein the cap element includes a centrally-located axial bore to accommodate the rod.

134. (Previously Presented) An assembly according to claim 91 wherein the rod has a knob element attached at its proximal end.

135. (Previously Presented) An assembly according to claim 133 wherein the rod includes a section that extends through and beyond the cap element.

136. (Previously Presented) An assembly according to claim 135 wherein a knob element is connected to the rod at the section that extends beyond the cap element.

137. (Previously Presented) An assembly according to claim 135 further comprising a sealing gasket between the spring element and the threaded portion of the spring housing, said gasket having a centrally located aperture in alignment with the axial bore to accommodate the rod.

138. (Previously Presented) An assembly according to claim 131 further comprising a disc element located between the spring element and the distal end of the spring housing, said disc element being connected to the rod and sized to slide inside the spring housing along with movement of the rod so as to compress the spring element by displacement of the disc in the proximal direction or to decompress the spring element by displacement of the disc in the distal direction.

139. (Previously Presented) An assembly with proximal and distal ends for bone, tissue and/or duct dilatation of a living being comprising in combination:

- (a) an inflatable and deflatable medical balloon having a balloon interior;
- (b) a conduit defining a channel for accessing the balloon interior from a location outside a living body when the balloon is positioned inside the living body;
- (c) a rod having proximal and distal ends extending through the channel to the balloon at the distal end of the rod;

(d) a spring element capable of temporarily applying axial and/or rotational forces to the balloon by means of the rod causing the balloon to elongate, or to wrap around the rod, or both, said spring element being housed in a spring housing section located at the proximal end of the assembly and fluidically isolated from the channel; and,

(e) a knob element connected to the proximal end of the rod for manual manipulation of the rod; and,

further comprising a spring housing section having proximal and distal ends for housing the spring element, the spring housing including a threaded portion at its proximal end and also comprising a threaded cap element sized to mate with the threaded portion of the spring housing, wherein the cap element includes a centrally-located axial bore to accommodate the rod, the rod including a section that extends through and beyond the cap element; and,

further comprising a sealing gasket between the spring element and the threaded portion of the spring housing, said gasket having a centrally located aperture in alignment with the axial bore to accommodate the rod.

140. (Previously Presented) An assembly according to claim 139 wherein the cap element is loosely threaded onto the spring housing such that there is no compression of the spring element and substantially no axial force is applied by the rod to the balloon element, which is in an uninflated state.

141. (Previously Presented) An assembly according to claim 139 wherein the cap element is screwed onto the spring housing thereby at least partially compressing the spring element toward the distal end, while the balloon element is in an uninflated state.

142. (Previously Presented) An assembly according to claim 139 wherein the cap element is screwed onto the spring housing thereby at least partially compressing the spring element toward the distal end, and the balloon element is at least partially inflated such that the distal end of the balloon applies an axial force to the rod causing it to displace the disc element in a proximal direction so as to additionally compress the spring element beyond the compression obtained by screwing the cap element onto the spring housing.

143. (Previously Presented) An assembly according to claim 139 wherein the cap element is screwed onto the spring housing thereby at least partially compressing the spring element toward the distal end, and the balloon element is fully inflated such that the distal end of the balloon applies an axial force to the rod causing it to displace the disc element in a proximal direction so as to additionally compress the spring element beyond the compression obtained by screwing the cap element onto the spring housing.

144. (Previously Presented) An assembly according to claim 143 further comprising a source of pressurized fluid which is supplying the pressurized fluid to the

balloon element and causing additional displacement of the disc element in a proximal direction.

145. (Previously Presented) An assembly according to claim 143 wherein pressurized fluid is not being supplied to the balloon element causing the balloon element to be in a deflating state which releases the axial force applied by the distal end of the balloon to the rod such that the force exerted by the compressed spring element on the rod becomes greater than the force of the deflating balloon and the disc element is displaced in a distal direction thereby stretching and tensioning the balloon element.